



In re Application of: PARIKH et al.  
 Application No. 09/443,863  
 Filed: November 19, 1999  
 For: DISPERSIBLE PHOSPHOLIPID STABILIZED MICROPARTICLES

COMMISSIONER FOR PATENTS  
 Washington, D.C. 20231

Sir:

Transmitted herewith is a response in the subject application.

☐ Applicants claim small entity status of this application under 37 CFR 1.27.

☒ Petition for Extension of Time

☐ Applicants petition for a one-month extension of time under 37 CFR 1.136, the fee for which is \$110.00 (enclosed).

☒ Applicants believe that no petition for an extension of time is necessary. However, to the extent that such petition is deemed necessary, Applicants hereby petition for a sufficient extension of time to render the present submission timely. Please charge Deposit Account No. 12-1216 for the appropriate petition fee.

☒ No additional claim fee is required.

☐ Other:

The claim fee has been calculated as shown below:

					SMALL ENTITY		OTHER THAN A SMALL ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	EXTRA CLAIMS PRESENT	RATE	ADDIT. CLAIM FEE	RATE	ADDIT. CLAIM FEE
TOTAL		MINUS		=	x 9=	\$	x 18=	\$
INDEPENDENT		MINUS		=	x 42=	\$	x 84=	\$
<input type="checkbox"/>	FIRST PRESENTATION OF MULTIPLE CLAIM				+ 140=	\$	+ 280=	\$
					TOTAL	\$	TOTAL	\$

☐ Please charge my Deposit Account No. 12-1216 in the amount of \$ . A duplicate copy of this sheet is attached.

☐ A check in the amount of \$ is attached.

☒ The Commissioner is hereby authorized to charge any deficiencies in the following fees associated with this communication or credit any overpayment to Deposit Account No. 12-1216. A duplicate copy of this sheet is attached.

☒ Any filing fees under 37 CFR 1.16 for the presentation of extra claims.

☒ Any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,

*Shannon Schemel*

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Date: July 10, 2003  
 SDS:ves



Attorney Docket No. 401930/SKYE PHARMA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

PARIKH et al.

Application No. 09/443,863

Art Unit: 1615

Filed: November 19, 1999

Examiner: G. Kishore

For: DISPERSIBLE PHOSPHOLIPID  
STABILIZED MICROPARTICLES

33/ #Amndt/H  
7/28/03  
RECEIVED  
JUL 14 2003  
PATENT  
TECH CENTER 1600/2900

### RESPONSE

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Non-Compliant Amendment (Voluntary Revised Practice), Applicants have recast the Amendment as set forth below. A copy of the Notice is attached.

Please enter the following amendments and consider the following remarks.

### AMENDMENTS

#### *IN THE SPECIFICATION:*

Replace the paragraph beginning at page 3, line 9 with:

HI

US Patent 5,302,401 describes a method to reduce particle size growth during lyophilization. It discloses a composition containing particles having a surface modifier adsorbed onto the surface together with a cryoprotectant, the cryoprotectant present in an amount sufficient to form a nanoparticle-cryoprotectant composition. A preferred surface modifier is polyvinylpyrrolidone, and a preferred cryoprotectant is a carbohydrate such as sucrose. Also described are methods of making particles having a surface modifier adsorbed on to the surface and a cryoprotectant associated with it. The patent refers specifically to 5% Danazol with 1.5% PVP and sucrose (2%) or mannitol (2%) as the cryoprotectant. Thus while various cryoprotectants are available and function adequately to protect the active agent during lyophilization, the solid product that results is often difficult to redisperse in aqueous media.